510(k) Summary

As required by 21 CFR 807.92(c)

OCT 2 0 2006

510(k) Number: K062251

Date Prepared: August 2, 2006

1. Submitter Information:

Submitter's Name/ Address:	St. Jude Medical 14901 DeVeau Place Minnetonka, MN 55345-2126
Contact Person:	Glenn Jacques Regulatory Affairs Manager Tel: 952-351-1356 Fax: 952-930-9481 gjacques@sjm.com

2. Device Information:

Trade Name:	Reflexion Spiral™ Variable Radius Catheter
Common Name:	Catheter, electrode recording
Classification Name:	Catheter, electrode recording or probe, electrode recording
Class:	Class II, 21 CFR 870.1220, Product Code DRF

3. Predicate Device:

Irvine Biomedical, Inc., (IBI) Inquiry™ Optima™ Steerable Electrophysiology Catheter (K042775)

4. Device Description:

The St. Jude Medical (SJM) Reflexion Spiral™ Variable Radius Catheter (Reflexion Spiral catheter) is a flexible, asymmetric, bi-directional, radiopaque variable radius loop electrophysiology catheter constructed of a polymer shaft that incorporates platinum electrodes.

The Reflexion Spiral catheter has a proximal handle (ComfortGrip™) that contains: 1) A shaft actuator mechanism for varying the asymmetrical sweep (90° sweep) and curl (180° curl) of the distal portion of the shaft. 2) A loop actuator mechanism for varying the loop diameter from approximately 25mm to approximately 15mm. 3) An electrical connector fitted into the proximal end of the handle.

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5. Indications for Use:

The Reflexion Spiral catheter can be used for recording intracardiac signals and for cardiac stimulation during electrophysiology studies. The Reflexion Spiral catheter is to be used to map the atrial regions of the heart.

6. Statement of how the technological characteristics of the device compare to those of the predicate or legally marketed device:

The Reflexion Spiral catheter and the predicate IBI Inquiry™ Optima™ catheter are both intended for electrogram recording and stimulation during electrophysiological studies. The different proximal handles show equivalent performance of the loop radius control and sweep/curl positioning control and does not affect the intended use or the scientific technology of the device.

7. Brief summary of non-clinical tests and results:

The test plan for the Reflexion Spiral catheter was based on FDA Guidance "Electrode Recording Catheter Preliminary Guidance, Draft Version," March 1995 and ISO 10555-1, Sterile Single-Use Intravascular Catheters Part 1: General Requirements. The test results indicate conformance to the standards and reliable performance when used in conformance with the device Instructions for Use. The Reflexion Spiral catheter does not raise any new issues of safety, effectiveness or performance of the device.

8. Statement of Equivalence:

Through the comparison data, the equivalence evaluation, and supporting bench and animal data, SJM considers the Reflexion Spiral™ Variable Radius Catheter to be substantially equivalent to the Irvine Biomedical, Inc. Inquiry™ Optima™ Steerable Electrophysiology Catheter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 0 2006

St. Jude Medical
Atrial Fibrillation Division
c/o Mr. Glenn Jacques
Regulatory Affairs Manager
14901 DeVeau Place
Minnetonka MN 55345

Re: K062251
Trade/Device Name: Reflexion Spiral Variable Radius Catheter, Model 402804
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode Recording Catheter or Electrode Recording Probe
Regulatory Class: II
Product Code: DRF
Dated: August 2, 2006
Received: August 4, 2006

Dear Mr. Jacques:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

B Zuckerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(K) Number (if known): K062251

Device Name: Reflexion Spiral™ Variable Radius Catheter

Indications for Use:

The Reflexion Spiral™ catheter can be used for recording intracardiac signals and for cardiac stimulation during electrophysiology studies. The Reflexion Spiral™ catheter is to be used to map the atrial regions of the heart.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K062251